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K962932

PREMARKET NOTIFICATION
Cordis Corporation
STABILIZER™ Plus XS Steerable Guidewire

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions

Common or Usual Name: Catheter Guide Wire

Proprietary Name: Cordis STABILIZER Plus XS Steerable Guidewire

II. Name of Predicate Devices

Cordis WIZDOM Steerable Guidewire (K953760)
Meditech/Boston Scientific Platinum Plus™ Guidewire (K935997)
Scimed/Boston Scientific Platinum Plus™ Coronary Guidewire

III. Classification

Catheter Guide Wire, Class II - 21 CFR 870.1330
74DQX - Cardiovascular

IV. Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description

The Cordis STABILIZER Plus XS Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.

The Cordis STABILIZER Plus XS Steerable Guidewire is an extra support version of the Cordis WIZDOM Steerable Guidewire. The extra support versions of the WIZDOM Steerable Guidewire utilize slightly larger diameter corewires and different tapers compared to the conventional WIZDOM guidewire in order to provide the extra support required for bulkier device (such as a stent) introduction.

VI. Biocompatibility

The materials incorporated into the STABILIZER Plus XS are exactly the same as the materials used for the currently marketed WIZDOM Steerable Guidewire.